UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,263	01/26/2001	James Thompson	IRVN-005CIP	7988

7590 06/05/2002

Carol L. Francis
BOZICEVIC, FIELD & FRANCIS LLP
200 Middlefield Road, Suite 200
Menlo Park, CA 94025

EXAMINER
YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/05/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/771,263	Applicant(s) THOMPSON ET AL.	
	Examiner Christopher H Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,13,14,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group 1, claims 1-15 in Paper No. 4 is acknowledged. Amendments to the claims have been made on the record, and claims 25 and 26 are newly added. Claims 1-15, 25 and 26 are examined on the record.

Specification

2. The disclosure is objected to because of the following informalities: there are numerous typographical errors through out the specification, including spelling, grammatical and erroneous punctuation, for example see pages 10,11, 15, 16, 19, 20, 34, 48, etc.

Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1,2,5,9,11,13,14,25, and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,203,787.

The claims in the present application and the U.S Patent No. 6,203,787 are each drawn to a ~~process~~ of a pharmaceutical composition either containing (U.S. Patent) or comprising (instant application) alloactivated lymphocytes that are used to generate an anti-tumor immunological response. The composition of the instant application and the U.S. Patent differ from one another in terms of the contents of each pharmaceutical composition, wherein the instant application comprises the components disclosed in the U.S. Patent, and other components not specifically disclosed. However, the examiner has found the pharmaceutical composition of the instant application to be substantially obvious over the pharmaceutical product of the U.S. Patent, because the basic components, the method of co-culturing, and the method of determination of sufficient alloactivation of the instant application are already recited in the U.S. Patent. Considerable overlap is noted in the source of the lymphocytes (see claim 2 of instant application and claim 1 of U.S. Patent); method of alloactivation (see claim 9 of instant application and claim 9 of U.S. Patent); duration and determination steps for thorough alloactivation of lymphocytes (see claims 11, 13, and 14 of instant application and claim 4 of the U.S. Patent).

Accordingly, the claimed products in the instant application and the U.S. Patent are obvious variants. Therefore, the inventions are co-extensive.

5. Claims 1,2,5,9,11,13,14,25, and 26 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent 6,203,787.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The claims of the instant application are drawn to a pharmaceutical composition comprising alloactivated lymphocytes, wherein the lymphocytes are from at least two donors, utilized for the generation of an anti-tumor immunological response. In addition, the instant application recites the means of administration, co-culturing limitations,and

determinants for effective and sufficient alloactivation. U.S. Patent 6,203,787 is drawn to a pharmaceutical composition containing, alloactivated lymphocytes from two donors, methods of administration of the pharmaceutical composition, co-cultuign techniques and methods, and specific determinants for adequate and sufficient alloactivation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to develop a pharmaceutical composition comprising alloactivated lymphocytes, because the prior art provides sufficient motivation to practice the invention as claimed. The suggestion/motivation for doing what the applicant has claimed is that it was already known in the art at the time of the invention that a method and a pharmaceutical composition containing the alloactivated lymphocytes, derived from two donor populations was available. Furthermore, it would be obvious to simply add other ingredients to a composition as to not substantially effect the activity of the basic compound. One would expect a reasonable amount of success in producing this pharmaceutical composition because the U.S. Patent No. 6,203,787 has already disclosed success in clinical trials, in animal models, and also commercial production of the composition.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2-5,26, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohler PC *et al.* (Cancer Immunol Immunother 1988; 26(1):74-82). Claims 1, 2-5, 26, and 9 are drawn to a pharmaceutical composition comprising alloactivated lymphocytes, wherein the donor lymphocyte cells are from at least 2, 3, or 4 different humans, wherein lymphocytes from at least one human is inactivated, and wherein the lymphocytes are alloactivated *ex vivo* for a time sufficient for compound to elicit an immune response. Kohler PC *et al.* disclose of alloactivated lymphocytes that are pooled from several patients, wherein the lymphocytes from at least one donor is inactivated, wherein the lymphocytes are alloactivated *ex vivo* for a time sufficient to generate an immune response (pg 75 Material and Methods Section). The claims are therefore anticipated.

8. Claims 1, 2, 8, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Philips *et al.* (J. Exp. Med. 1984 Apr 1; 159(4):993-1008). Claims 1, 2, 6-8 are drawn to a pharmaceutical composition comprising alloactivated lymphocyte, wherein the lymphocytes are from multiple donors, and the alloactivated cells are co-cultured with cells expressing HLA-DR. Philips *et al.* disclose of a composition comprising alloactivated lymphocytes, wherein the lymphocytes are from multiple donors, and the lymphocyte cells express HLA-DR (see pages 994-995, and 996). Therefore, the claims are anticipated.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kohler PC *et al.* (Cancer Immunol Immunother 1988; 26(1):74-82) in view of Phillips *et al.* (J. Exp. Med. 1984 Apr 1; 159(4):993-1008).

Claim 13 is drawn to a pharmaceutical composition comprising alloactivated lymphocytes, wherein the lymphocytes are alloactivated by co-culturing *ex vivo* for 12 hours to 5 days.

Kohler *et al.* and Phillips *et al.* both disclose of a composition comprising alloactivated lymphocytes, but Kohler specifically recites a pharmaceutical composition , but is silent with regards to the duration of co-culturing lymphocytes. Philips *et al.* however, specifically recite of a composition of lymphocytes wherein the lymphocytes are co-cultured for 5 days.

It would have been obvious to one of skill in the art at the time the invention was made to develop a pharmaceutical composition comprising alloactivated lymphocytes in a co-cultured for 5 days, because the art provides sufficient motivation to practice the invention as claimed. The suggestion/motivation for do what the applicant has claimed is that it was already known that compositions comprising alloactivated lymphocytes were available, and that a method of co-culturing to activate the lymphocytes were well known and established, wherein the activation required 5 days of co-culturing. It would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of Kohler and Phillips *et al.* to derive a pharmaceutical composition comprising alloactivated lymphocytes, wherein the lymphocytes are co-cultured for 5 days, because Kohler *et al.* and Philips *et al.* both showed relative success in using bith there products to generate a immune response.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
May 30, 2002.

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600